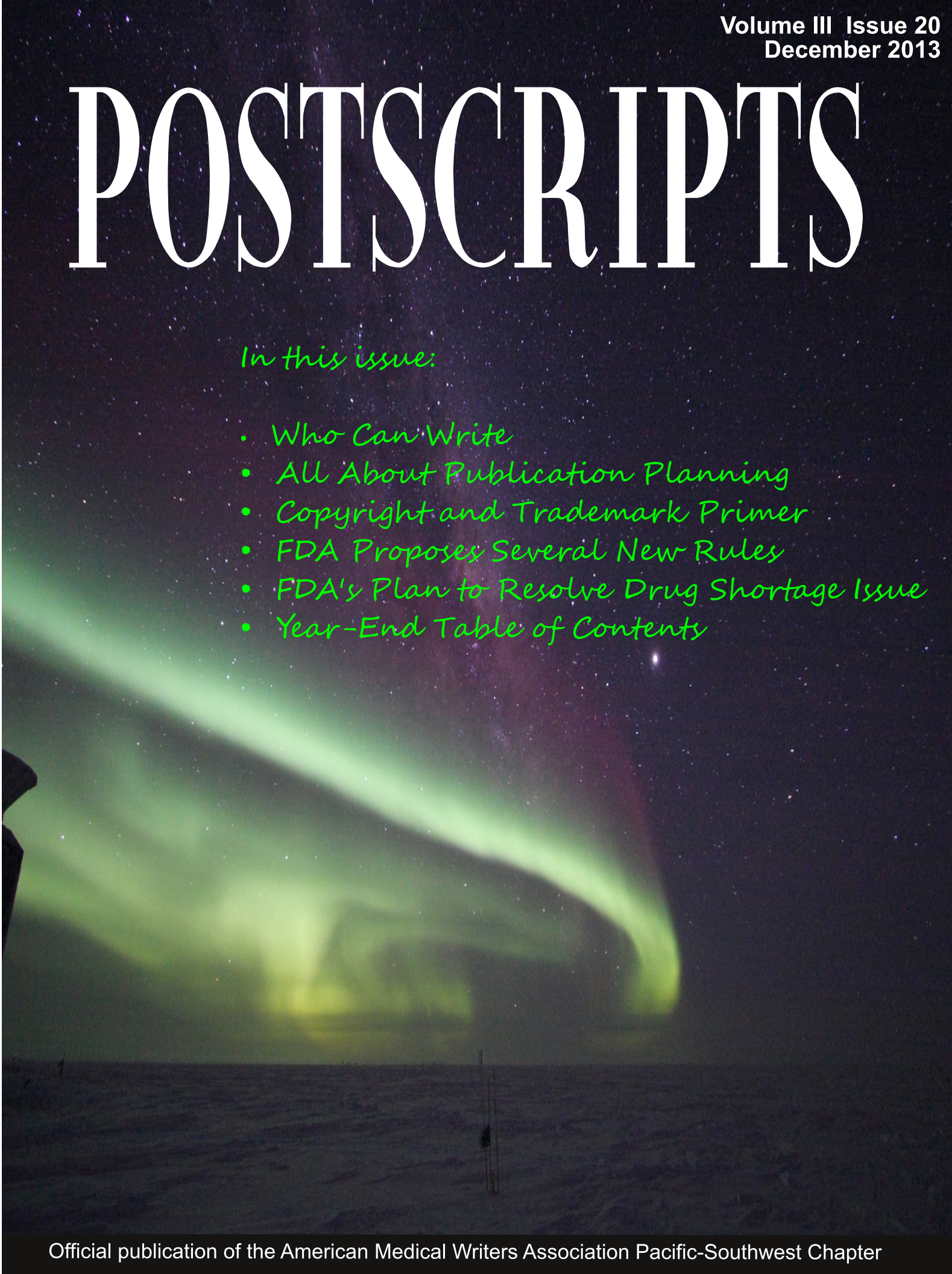
Volume III Issue 20
December 2013

POSTSCRIPTS



Official publication of the American Medical Writers Association Pacific-Southwest Chapter

Postscripts
December 2013
AMWA PacSW

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of Postscripts is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, Postscripts publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Additionally, to promote career and networking needs of the members, Postscripts includes news and event notices covering Chapter activities.

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SUBSCRIPTION

Postscripts is published monthly except in January and July. Subscription is included in the AMWA Pac-SW chapter membership which is automatic for all AMWA members with a mailing address in Southern California, Southern Nevada and all of Arizona. This newsmagazine is distributed on the 1st of each month. AMWA members can request past issues by sending an email to the editor.

INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike. Please contact editor.

ADVERTISING

Articles describing products and services relevant to medical writers may be considered or solicited. Members may submit advertisements for their services or products for free. Please contact editor for details.

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POSTSCRIPTS

December 2013 | Volume 3, No. 20

UPCOMING EVENTS AND DATES

January 23, 2014: Networking Happy Hour, 5 PM 'til... @ El Torito Mexican Restaurant & Bar, 17420 17th St (Hwy 55 ay 17th St), Tustin, CA. Hosts: Carolyn Bates and Heather Oliff.

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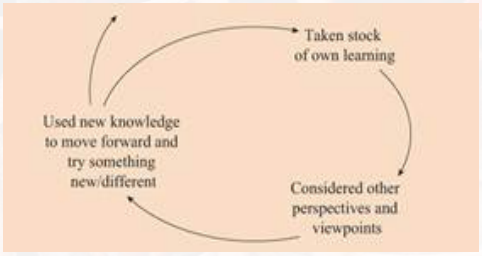
From the President's Desk

Greetings AMWA friends and colleagues,

The holiday season brings both celebration and reflection. We rejoice in our Lanie Adamson receiving the Golden Apple award at AMWA's National conference on November 8, and reflect fondly on the shared moments and informative educational events experienced at the event. We celebrate the engaging and enlightening webinar presented by Donna Simcoe on November 19, and its wonderful review prepared by James Sanchez for this month's Postscripts. And we take great delight in the festive moments shared at Jacki Dyck-Jones' beautiful AMWA holiday gathering (stay tuned for photos in our first 2014 issue!) Last, but by no means least, we applaud and thank the many wonderful contributors to our Newsmagazine, whose engaging articles enrich and inform us throughout the year.

Reflection entails not only looking backwards, but also looking forwards. As depicted in in "Learning to Learn" (http://labspace.open.ac.uk), thinking about what happened and when, what we valued and learned, provides clarity and an opportunity to use that knowledge to shape how we would like to see ourselves in the future, both as individuals and as members of a community. One "reflects forward" by thinking about what you might do in the future, and how this might be different from what was done in the past.



Circle of Learning

For our AMWA Chapter community, we strive to offer opportunities that add value to our professional lives by learning from we've done and striving to do even better in the future. Please take a moment when you shortly receive a survey gauging your interest in regional and/or local conferences, to provide information that can help us continue to offer meaningful educational experiences.

To kick off our 2014, we can look forward to new networking opportunities and causes for celebration!

- January 23: Happy Hour Networking event at El Toritos in Tustin, CA at 5 PM. Hosted by Heather Oliff and Carolyn Bates.
- January (date/location TBD): Rebecca Anderson to discuss the exciting story behind nevirapine use to address pediatric AIDS, as described in her SOON TO BE • • PUBLISHED BOOK on the topic (congratulations Rebecca!). You'll also get to learn firsthand about getting a book published.
- Also in January….the passing of the presidential gavel to Donna Simcoe. An exciting, new phase in our Chapter's "circle of learning".

It has been a great privilege and joy being Chapter president. Thank you all for a truly invaluable and memorable experience.

Happy Holidays to all!

Warmly,

Jenny

Jennifer Grodberg, PhD, RAC
President, AMWA Pacific-Southwest Chapter

Who Can Write?

By Jennifer Reichert, PhD, CMPP

Last year I attended the International Publication Planning Association's (TIPPA) annual meeting. The sessions were thought provoking and informative. Topics covered included those I have come to expect from these meetings, such as authorship criteria and acknowledgement, journal selection, and the roles of pharmaceutical companies in publications, as well as less common topics such as the value of health economics and outcomes research and negotiating with university grant administration offices. It is always a pleasure to get together with other publication professionals and share insights and experiences.

As always when publication professionals get together, we talked about writing—the writing process, writing quality, and "who can write." Throughout my career as a scientist, medical writer, and publication manager, I have frequently heard colleagues say things such as, "subject matter experts can't write," or "MDs can't write," or "business people can't write."

In one talk at TIPPA, a subject matter expert explained his process for developing manuscripts in his area of expertise. When asked if he liked to work with medical writers he said, "I prefer to do my own writing. When I work with a medical writer, I just have to re-write it myself anyway." Half an hour later, in a talk given by publication professionals from a medical communication company, a publication manager said she preferred to have medical writers write manuscripts because if subject matter experts wrote them, "we just have to re-write them anyway." I chuckled to myself and wondered if these two people who were sitting in the same room together were listening to each other.

As medical writers, we are familiar with the "re-writing" process. We are experts in written communication and adept at translating technical jargon into language which broader audiences at all levels can understand, without losing the important technical meaning of the message. This is the value of what we do. If subject matter experts speak jargon to each other and no one outside of their specialty can understand it, then they have not communicated to a larger audience.

I think it is important to be aware of the detrimental effects of making statements such as, "specialists can't write." When we say, "so-and-so can't write," we shut down the possibility that communication can occur. We are essentially saying that trying to understand what "so-and-so" has written is a waste of our time. We have lost awareness of our unique position as readers and assume that all readers share our position, therefore, no one could understand what has been written. As writers it is important to focus on the message and the audience and bring the two together. This is our expertise. This is what we do.

How we communicate with each other, with publications professionals, and with academic and industry experts about "who can write" can foster communication and build collaborative relationships. It can help us to learn how better to apply our skills to a given topic and build respect and long term relationships with our collaborators. Next year, I encourage you to be aware of the negative message we convey when we say, "we just have to re-write it anyway," to value and build the collaborative process and avoid saying anyone can't write. By doing so, we may also teach an academic not to say, "medical writers can't write."

I would like to close by sharing two links related to collaboration in writing. The first is an excerpt from an NPR interview with novelist Claire Messud. This excerpt describes the value of a good editor. How lucky she is to have one in her husband, James Wood.

(continued on next page)

On living with her husband, New Yorker fiction critic James Wood

"He's my first reader and we know each other very well and, unless he thinks something is disastrous, in the first instance he's encouraging and vague: 'Keep at it. Keep going' and when there's a draft and it's possible to be a more critical reader in a productive way, then he will be, but if I showed him 20 pages, he won't start doing line edits or say, 'This character needs more development on page four,' you know. He won't do that. He'll just say, 'Keep going. That's great.' ... But he will [be more critical] later on. He's well trained."

http://www.npr.org/2013/05/09/180875256/the-woman-upstairs-a-saga-of-anger-and-thwarted-ambition

The second is a link to The People's Science an interactive forum for scientists to share their work with people outside of their area of expertise and strike up a "conversation" with them about their work.

http://thepeoplesscience.org/index.html

What's Up(!) . . . at FDA

By Sally Altman and Kelly Dolezal

In November, the FDA approved treatments for chronic lymphocytic leukemia; partial-onset seizures; mantle cell lymphoma; interdigital tinea pedis, tinea cruris, and tinea corporis; and chronic hepatitis C. The FDA proposed several new rules, including those to limit foodborne illnesses transmitted in animal feed and to address drug shortages. Several drug companies were disciplined for violating regulations this month, the most notable of which was Janssen Pharmaceuticals, Inc., who will owe $1.67 billion for misbranding its drug Risperdal.

FDA Announcements

10-21-13	The FDA awarded $15 million in grants to develop treatments for rare diseases and conditions that affect less than 200,000 people in the U.S. (for drugs), or for which there is no expected development of treatment (for medical devices). More than 30 million people in the U.S. are estimated to suffer from a rare disease.[1]
10-21-13	The FDA is seeking a permanent injunction against James G. Cole, Inc., an Oregon dietary supplement manufacturer, for repeatedly distributing unapproved drugs and adulterated dietary supplements.[2]
10-22-13	Sterile products produced by Specialty Medical Compounds Pharmacy (Michigan) are being voluntarily recalled. These products include those intended for human and animal patients.[3]
10-23-13	In December 2013, the FDA will finish phasing out inhalers containing chlorofluorocarbons (CFCs), which damage the ozone layer; only 2 inhalers with CFCs are still on the market. The CFCs are replaced with hydrofluoroalkanes (HFAs) that serve the same propellant function. [4]
10-25-13	The FDA proposed a rule to require makers of animal feed and pet food to plan and implement procedures to prevent foodborne illnesses. This new rule would be part of the Food Safety Modernization Act.[5]
10-31-13	The FDA proposed a rule that would require drug manufacturers to give early notice of permanent or temporary interruptions to production that could cause drug shortages.[6]
11-4-13	Janssen Pharmaceuticals, Inc. (JPI) (New Jersey) pleaded guilty to a charge of misbranding their drug Risperdal. Risperdal was initially approved for treatment of schizophrenia, acute mania, and Bipolar 1 Disorder, but JPI marketed the drug for unapproved use in children with behavior challenges and in elderly patients with dementia-related agitation, despite known health risks to both groups. JPI will owe $1.67 billion in combined criminal and civil fines.[7]

Selected FDA Approvals

Drug	Indication	Company
GAZYVA[8]	Approved on November 1, GAZYVA is a cytolytic antibody indicated for treatment (in conjunction with chlorambucil) of previously untreated chronic lymphocytic leukemia.[9]	Genentech
APTIOM[10]	Approved on November 8, APTIOM is indicated for adjunctive treatment of partial-onset seizures.[11]	Sunovion
Imbruvica[12]	Approved on November 13, Imbuvica is indicated for treatment of mantle cell lymphoma in patients having received prior therapy.[13]	Pharmacyclics
Luzu[14]	Approved on November 14, Luzu is a topical azole antifungal cream indicated for treatment of interdigital tinea pedis, tinea cruris, and tinea corporis in adults.[15]	Medicis
OLYSIO[16]	Approved on November 22, OLYSIO is indicated for treatment of chronic hepatitis C as part of an antiviral treatment regimen.[17]	Janssen

(continued on next page)

For additional information, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm.

[1]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm371503.htm [Link]
[2]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm371516.htm [Link]
[3]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm371866.htm [Link]
[4]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm371901.htm [Link]
[5]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm371901.htm [Link]
[6]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm373044.htm [Link]
[7]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm373499.htm [Link]
[8]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails [Link]
9http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125486s000lbl.pdf [Link]
[10]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails [Link]
[11]http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022416s000lbl.pdf [Link]
[12]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.NewOriginalNDA [Link]
[13]http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/205552s000lbl.pdf [Link]
[14]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails [Link]
[15]http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204153s000lbl.pdf [Link]
[16]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails [Link]
[17]http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/205123s000lbl.pdf [Link]

"To become aware of the possibility of search is to be on something. Not to be onto something is to be in despair."

— from *The Year of Fog* by Michelle Richmond

What's Up(!) . . . at EMA

By Wim D'Haeze

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (26 OCT 2013 THROUGH 24 NOV 2013)

The alerts listed below cover the period from October 26, 2013 through November 24, 2013. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to What's New on the EMA website.

GUIDELINES

• Regulatory and procedural guideline: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure[a]

REPORTS/PAPERS

• None to report

APPROVALS/REFUSALS

Compound	Indication/Use	Applicant	Advice [Note]
Sovaldi[b]	Sovaldi is indicated in combination with other medicinal products for the treatment of chronic hepatitis C in adults	Gilead Sciences International Ltd.	Positive opinion
Cholic Acid FGK[c]	Treatment of inborn errors of primary bile acid synthesis, in infants from one month of age for continuous lifelong treatment through adulthood, encompassing the following single enzyme defects: sterol 27-hydroxylase (presenting as cerebrotendinous xanthomatosis, CTX) deficiency, 2- (or α-) methylacyl-CoA racemase (AMACR) deficiency, cholesterol 7 α-hydroxylase (CYP7A1) deficiency	FGK Representative Service GmbH	Positive opinion
Tivicay[d]	Indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age	ViiV Healthcare	Positive opinion
Xigduo[e]	Indicated in adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control	Bristol-Meyers Squibb/AstraZeneca EEIG	Positive opinion
Masican[f]	Gastrointestinal stromal tumour	AB Science	Negative opinion
Zoledronic Acid Accord[g]	Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone and treatment of tumour-induced hypercalcaemia	Accord Healthcare Ltd.	Positive opinion

(continued on next page)

PAS-GR[h]	Indicated for use as part of an appropriate combination regimen for multi-drug resistant tuberculosis in adults and paediatric patients from 28 days of age and older when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability	Lucane Pharma SA	Positive opinion
Deltyba[i]	Indicated for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability	Otsuka Novel Products GmbH	Positive opinion

Note: “positive” or “negative” opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards of granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

GENERAL ANNOUNCEMENTS

• New EMA guidance on development of antibacterials to help in the fight against multidrug-resistant pathogens.[j]
• European Medicines Agency launches public catalogue of medicine shortages assessed by the Agency.[k]
• European Medicines Agency explores ways to further involve patients in the benefit-risk assessment of medicines.[l]

LINKS

EMA Website - What's New:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/whats_new.jsp&mid=WC0b01ac058004d5c4 [Link]

a.http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500003981 [Link]

b.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/smops/Positive/human_smop_000612.jsp&mid=WC0b01ac058001d127 [Link]

c.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002081/smops/Positive/human_smop_000610.jsp&mid=WC0b01ac058001d127 [Link]

d.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002753/smops/Positive/human_smop_000611.jsp&mid=WC0b01ac058001d127 [Link]

e.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002672/smops/Positive/human_smop_000622.jsp&mid=WC0b01ac058001d127 [Link]

f.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002670/smops/Negative/human_smop_000621.jsp&mid=WC0b01ac058001d127 [Link]

g.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002667/smops/Positive/human_smop_000614.jsp&mid=WC0b01ac058001d127 [Link]

h.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002709/smops/Positive/human_smop_000618.jsp&mid=WC0b01ac058001d127 [Link]

i.http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002552/smops/Positive/human_smop_000572.jsp&mid=WC0b01ac058001d127 [Link]

j.http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/11/news_detail_001944.jsp&mid=WC0b01ac058004d5c1 [Link]

k.http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/11/news_detail_001940.jsp&mid=WC0b01ac058004d5c1 [Link]

l.http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/10/news_detail_001934.jsp&mid=WC0b01ac058004d5c1 [Link]

AMA-zing Style — the AMA Manual of Style Column

By Dikran Toroser, PhD, Amgen Inc.

Copyright and Trademark—a primer

Who owns the scientific article you have just helped your authors create? How does copyright differ from trademark? The medical writer would be well served to be familiar with the copyright- and trademark-related information available in the AMA manual of Style 10th edition. This summary is not intended to serve as legal advice.

Copyright: a Definition. Copyright is a term used to describe the legal right of authors to control the communication and reproduction of their original works. Few thoroughly understand copyright law and its basic applications in scientific publishing.

History. In 1710, England created the first copyright act. Article 1, section 8, of the US Constitution, adopted in 1787, serves as the foundation for US copyright law. More recently, for works created after 1978, US law automatically provides protection to the creator of the work at the time it is created, whether or not the work is published. Under US copyright law, the employer is the legal author of a work-made-for-hire.

Copyright Assignment or License. Typically, copyright vests initially with the author. An author may transfer rights to a publisher by copyright assignment, exclusive license, or nonexclusive license. A broadly worded exclusive license may provide much of the same rights to publishers as would a copyright assignment. A nonexclusive license permits a publisher certain rights to publish and disseminate work, but the copyright remains with the author.

Publishers that make substantial investments in their products typically seek assignments from authors of written works. However, increasing demands by authors and their institutions and the increasing complexity of modern publishing models will undoubtedly lead to much future debate among authors, institutions, and publishers with regard to copyright assignments, licenses, and publication. In general, however, as a condition of considering a work for publication, many publishers of scientific journals require authors to assign copyright or an exclusive publication license in the event that the work is published. There is no international copyright law *per se*. Thus, copyright laws do not automatically protect an author's work throughout the world. However, most countries offer protection to works from other nations. For example, most industrialized nations and many developing countries are signatories to conventions that can serve to protect works created in other member countries.[1]

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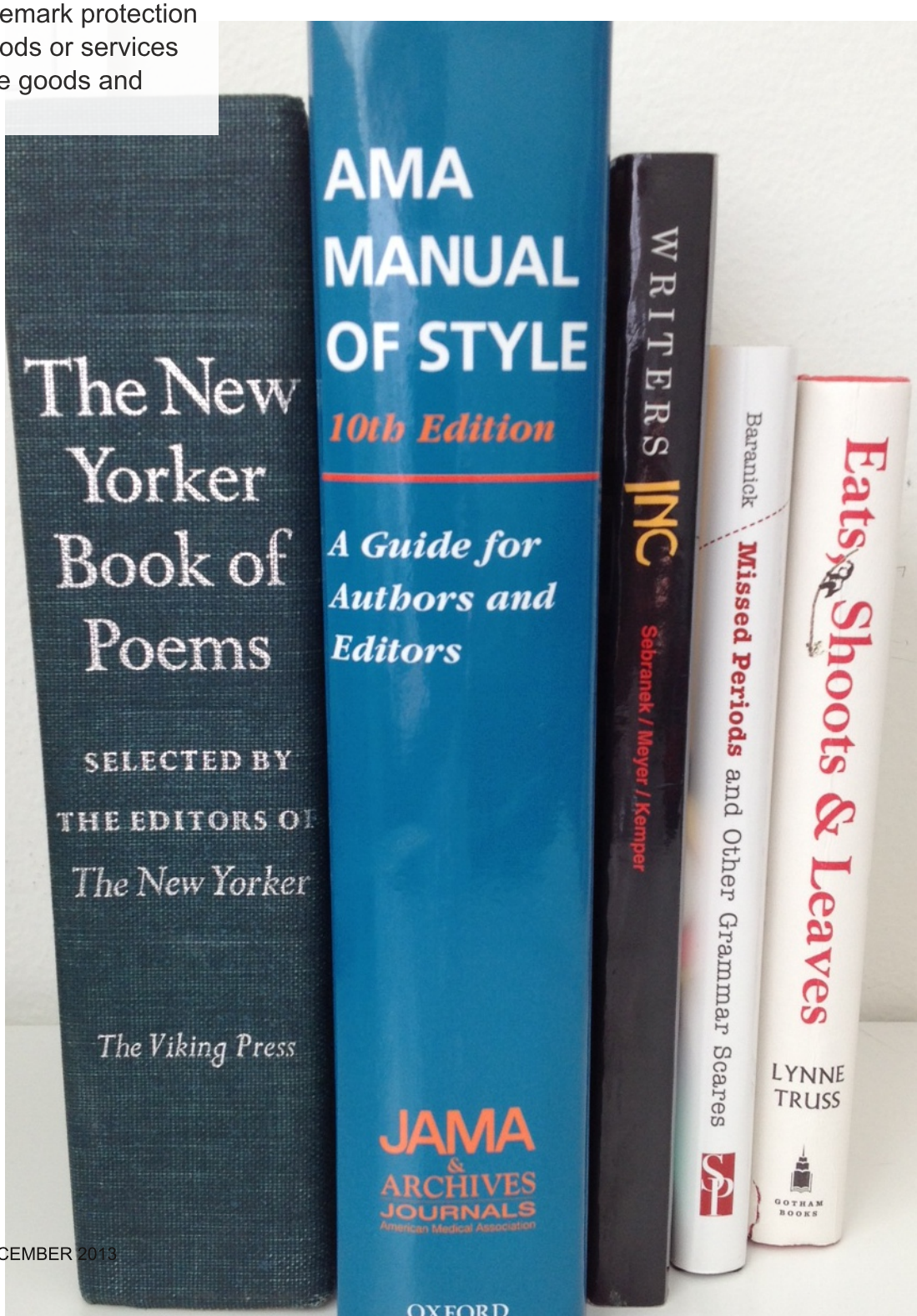
Trademark. Trademark and unfair-competition laws are designed to prevent a competitor from

(continued on next page)

selling goods or services under the auspices of another. *Trademarks* are legally registered words, names, symbols, sounds, or colors or any combination of these items that are used to identify and distinguish goods from those goods manufactured and sold by others and to indicate the source or origin of the goods (eg, brand names). To receive trademark status, a mark must be distinctive (ie, not similar to other marks) and not generic or merely descriptive of a category of products. Logos, designs, or symbols may also receive trademark protection if they distinguish particular goods or services and identify the source of those goods and services.

References

1. http://www.copyright.gov/fls/fl100.html (accessed Nov 11, 2013) [Link]
2. http://www.copyright.gov/title17/92chap1.html (accessed Nov 11, 2013) [Link]



de-MS-tifying Word

By Susan Chang, PhD, Susan Chang Consulting
and Alyssa Wu-Zhang, PhD

As a medical communicator, it's not enough to be an excellent writer/editor. We must be fast, too! We hope these PC shortcuts give you more time for family, friends, and pie this holiday season. Look for the Mac version of these tips in a future column!

PUT YOURSELF ON THE MAP

An easy way to jump to specific sections of a document is to use the navigation window. This works if the sections of your document have Heading Styles applied.

PC: Go to **View** tab → **Show/Hide** → Check **Document Map** (2007) / **Navigation Pane** (2010)

A navigation window will open on the left with a miniature outline of your document. Click on any heading to go straight to that section.

FAVORITE KEYBOARD SHORTCUTS (PC)

Formatting Shortcuts		Movement, View, & Text Selection Shortcuts	
Bold	[Ctrl] B	Follow hyperlink[1]	[Ctrl] click hyperlink
Copy	[Ctrl] C	Return to hyperlink[2]	[Alt] [←] (left arrow key)
Find	[Ctrl] F	Return to last edit	[Shift] F5
Italics	[Ctrl] I	Go to page #, table #, etc	[Ctrl] G
Hyperlink	[Ctrl] K	Beginning of document	[Ctrl] [Home]
New document	[Ctrl] N	End of document	[Ctrl] [End]
Save	[Ctrl] S	Beginning of current line	[Home]
Underline	[Ctrl] U	End of current line	[End]
Paste	[Ctrl] V	Top of preceding page	[Ctrl] [Page Up]
Cut	[Ctrl] X	Top of next page	[Ctrl] [Page Down]
Redo	[Ctrl] Y	Next table cell	[Tab]
Undo	[Ctrl] Z	Zoom in	[Ctrl] scroll up (mouse wheel)
Indent text (table cell)	[Ctrl] [Tab]	Zoom out	[Ctrl] scroll down (mouse wheel)
Indent text (body text)	[Tab]	Select all	[Ctrl] A
Nonbreaking hyphen	[Ctrl] [Shift] -	Select sentence	[Ctrl] click inside sentence
Nonbreaking space	[Ctrl] [Shift] [Space]	Select word	double-click a word
Superscript font	[Ctrl] [Shift] +	Select paragraph	triple click inside paragraph
Subscript font	[Ctrl] +	Select line of text	click to the left of the line ↗
Soft return	[Shift] [Enter]	Select table row	click to the left of the row ↗
Show formatting	[Shift] F1	Select table column	click above the column ↓
Update fields	Select field [F9]	Select entire table[3]	[ALT] double-click inside the table

[1] This is the default shortcut. Advanced Word settings allow you to turn this off so that clicking [Ctrl] is not required; however, the default setting is helpful if you frequently edit hyperlinks created using the shortcut [Ctrl] K.

[2] [Alt] [←] (left arrow key) takes you back to the hyperlink you clicked most recently. This feature is priceless when QCing tables of contents (TOCs) and numerous cross-references!

[3] [ALT] double-click is a good option when ⊞ isn't in the upper left-hand corner of table. This shortcut will also open a "research" window pane to the right of the page, but it can be closed easily.

Word woes?
Email us at SKC@SusanChangConsulting.com (PC) and AlyssaWPhD@gmail.com (Mac).

Chapter Meet and Greet at AMWA 2013 Meeting in Columbus, Ohio

Pictures by Kathy Boltz and collage by Ajay Malik.

Medical Publication Planning: A Webinar by Donna Simcoe

By James Sanchez, PhD, University of Southern California, Los Angeles

On November 19, AMWA members across the Pacific Southwest fired up their computers to "virtually" attend a Web-based presentation hosted by Donna Simcoe, MS, MBA, CMPP, the Publications Director at Cadence Pharmaceuticals, Inc. and a leading medical writer -- the chapter's president-elect, in fact! Donna gave an engaging and informative overview of publication planning in the pharmaceutical and medical device industries, a field that has changed in the last two to three decades and is still encountering new developments.

Publication planning, Donna explained, involves the dissemination of scientific and clinical information to professionals at meetings and in peer reviewed journals. A publication manager develops strategy and directs the team-based efforts that are part of submitting publications. Planning is indeed key. It is especially important to understand the current landscape in which there is increased vigilance against lack of transparency; conflicts of interest; and mis-reporting data or even withholding data. Both positive and negative results should be published.

Guidelines known as Good Publication Practice 2 (GPP2) provide recommendations and checklists which help improve transparency in reporting peer-reviewed research, and clarifying roles of various stakeholders including medical writers, external authors, etc. (http://www.bmj.com/content/339/bmj.b4330.long) are often followed. The International Committee of Medical Journal Editors (ICMJE) has also recently updated their set of uniform recommendations (www.icmje.org/urm_main.html) that include authorship criteria.

Authors are responsible for all aspects of the publication and a publication manager works closely with the authors to determine the direction of a publication. A publication steering committee, consisting of investigators who led or carried out clinical design and trial development, may be formed to develop and execute the publication plan. It is a collaborative exercise featuring the authors and if appropriate, the sponsor. The result is an increased transparency of the process, which reduces the chance of missed opportunities or publishing conflicting or confusing information.

Publication planners are also involved in budgeting resources that will be needed. Congress costs, such as travel, might be budgeted, and journal fees may be on the bill, too. The rise of open access journals, while presenting the option of having a full article publically available, may also come with a price that could range from one to ten thousand dollars. If the publication is to be developed with the help of a medical writer, data/statistical analysis or a medical communication agency, that will also need to be budgeted and acknowledged in the manuscript.

At the outset of a project, the publication manager shapes a schedule, taking into account hard deadlines such as congress abstract submission dates. The journal submission-to-publication timeline is also often a chief consideration, and it pays to have a backup plan in case of a rejection.

In addition to managing timelines, one of the most major decisions a publication planner must make has to do with the audience. Who will attend a certain congress? It is useful to know the makeup of the attendees and how the meeting dates correspond with the publication schedule. And which journal to choose, among the literally thousands in print? Factors influencing the decision include target audience, journal content, circulation, and a number of journal rankings, including impact factor and the very 21st century Altmetrics (http://altmetric.com), a measure of online attention. The final publication plan can be reevaluated every 6 months or so.

Donna ended the talk by highlighting that there are many avenues where medical writers can participate in publication development or planning. It is important to acknowledge medical writers' contributions in the acknowledgement section per GPP2, however, recently some journals have moved beyond GPP2 requiring medical writers be listed as authors.

With that, probably the first ever Webinar sponsored by the AMWA Pac-SW chapter came to a close. Many thanks to Donna for taking the time to let us all learn some more about publication planning!

Guidelines for Publication Professionals and Medical Writers

Compiled by Donna Simcoe, MS, MBA, CMPP
Cadence Pharmaceuticals, Inc.

- American Medical Writers Association (**AMWA**) Position Statement on the Contribution of Medical Writers to Scientific Publications. http://www.amwa.org/files/About%20Us/AMWA_PositionStatement_Contributions.pdf [Link]
- CAse REport guidelines (**CARE**) guidelines. http://blogs.biomedcentral.com/bmcblog/2013/10/09/care-guidelines/ [Link]
- Committee on Publication Ethics (**COPE**). http://publicationethics.org/ [Link]
- CONsolidated Standards of Reporting Trials (**CONSORT**). http://www.consort-statement.org/ [Link] ; http://jama.jamanetwork.com/article.aspx?articleid=193759 [Link]
- Council of Science Editors (**CSE**). White paper on Promoting Integrity in Scientific Journal publications. http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3313 [Link]
- European Medical Writers Association (**EMWA**). Increasing Author Disclosure Requirements: What Does This Mean For Medical Writers Involved In The Manuscript Development Process? http://www.emwa.org/Home/Webeditorial-2.html [Link]
- Enhancing the QUAlity and Transparency Of health Research (**EQUATOR**). http://www.equator-network.org/2013/10/31/reporting-guidelines-can-their-use-make-the-work-of-systematic-reviewers-and-guideline-developers-better/ [Link]
- FDA Good Reprint Practices guidelines. http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm [Link]
- Good Publication Practice for Communicating Company Sponsored Medical Research: The **GPP2** guidelines. http://www.bmj.com/content/339/bmj.b4330.full [Link]
- International Committee of Medical Journal Editors (**ICMJE**), Uniform Requirements for Manuscripts Submitted to Biomedical Journals. http://www.icmje.org/urm_main.html [Link]
- ORBIT II
- **PhRMA**, Principles on Conduct of Clinical Trials: Communication of Clinical Trial Results. http://www.phrma.org/sites/default/files/105/042009_clinical_trial_principles_final.pdf [Link]
- Standards for Quality Improvement Reporting Excellence(**SQUIRE**) guidelines. http://squire-statement.org/ [Link]
- **SANDRA** (Scale for the Assessment of Narrative Review Articles) and other scales to critically appraisal published research evidence. http://www.unisa.edu.au/Research/Sansom-Institute-for-Health-Research/Research-at-the-Sansom/Research-Concentrations/Allied-Health-Evidence/Resources/CAT/ [Link]
- STAndards for the Reporting of Diagnostic accuracy studies (**STARD**) guidelines. http://www.stard-statement.org/ [Link]
- World Association of Medical Editors (**WAME**) Conflict of Interest in Peer-Reviewed Medical Journals. http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals [Link]
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Contributors to the list: Roma Levy, MaryAnn Foote, Ajay Malik

Safety Sentinels: Pharmacovigilance Issues and News

By Ellen Klepack, PharmD

This month's column will feature FDA's announced plan to help resolve drug shortages.

On October 31, 2013, the FDA announced the release of their Strategic Plan for Preventing and Mitigating Drug Shortages (Strategic Plan) for review by congress and also proposed implementation of a rule that would expand the early notification of drug shortage requirement to include biologics.[1] Both actions in the announcement are in accordance with The Food and Drug Administration Safety and Innovation Act (FDASIA) that was signed into law in 2012. This act increased FDA's authority to require that all manufacturers of certain medically important prescription drugs, including biologics, notify FDA of any disruptions or discontinuations in supply at least six months prior, or as soon as practical. It also required the creation of a task force on drug shortages charged with developing a Strategic Plan to explore ways in which drug shortages could be mitigated or prevented.[1,2]

Drug Shortage Background

The number of prescription drug shortages has risen sharply over recent years. According to data compiled by the FDA, the number of new drug shortages increased from 56 in 2006 to 251 in 2011 (Figure1).[3] Areas most affected by shortages have been oncology, antibiotics, liquid nutrition, and anesthetics. The number of new shortages decreased to 117 in 2012 and has been credited to an executive order by President Obama in 2011, which directed FDA to use its existing authorities to broaden the reporting requirement of certain medically important prescription drugs and expand its efforts to expedite manufacturing regulatory reviews that could mitigate or avoid potential shortages (e.g., new manufacturing sites, suppliers, other manufacturing changes).[4] Quality and manufacturing issues have been the largest cause of shortages, accounting for 66% of supply disruptions in 2012 (Figure 2).[2]

Strategic Plan Highlights

The main goals of the Strategic Plan are to improve FDA's response to drug shortage notifications and to provide long term strategies that could prevent drug shortages by addressing their underlying causes.[2] Actions listed in the plan to improve response include streamlining FDA's internal processes and procedures to more efficiently handle drug shortage notifications, improving the tracking of shortages by creating one database specific to drug shortages, and clarifying roles and responsibilities of manufactures including when and how to notify FDA of a shortage and encouraging manufacturing practices that could reduce the likelihood of a shortage. External response improvements include enhancing FDA's drug shortage webpage and creating a smart phone application to provide real time notifications of shortages to the public.

To address the goal of long term prevention of drug shortages, the Strategic Plan recommends formation of an Office of Pharmaceutical Quality within the Center for Drug Evaluation and Research (CDER), broader use of metrics to evaluate manufacturing quality, exploring risk based approaches to identify early warning signals and manufacturing quality problems, and consideration of publically recognizing manufacturers who have demonstrated a consistent record of high quality manufacturing.[1,2]

Addressing the issue of drug shortages requires involvement from a variety of stakeholders. Additional areas where the FDA is limited to take action but could be considered by external stakeholders are also listed in the Strategic Plan as part of the overall effort to mitigate and prevent drug shortages.

(continued on next page)

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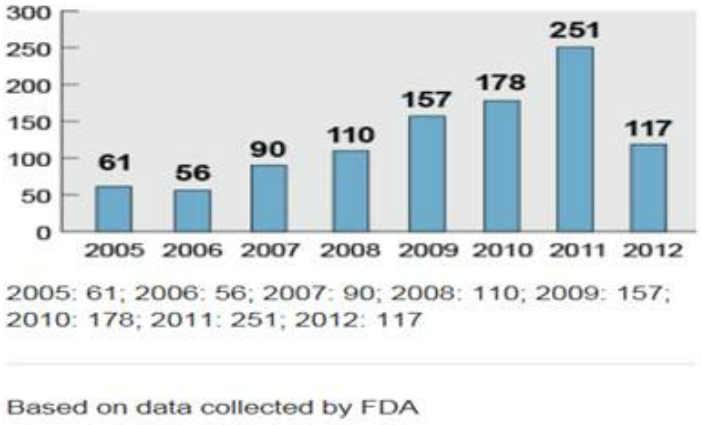
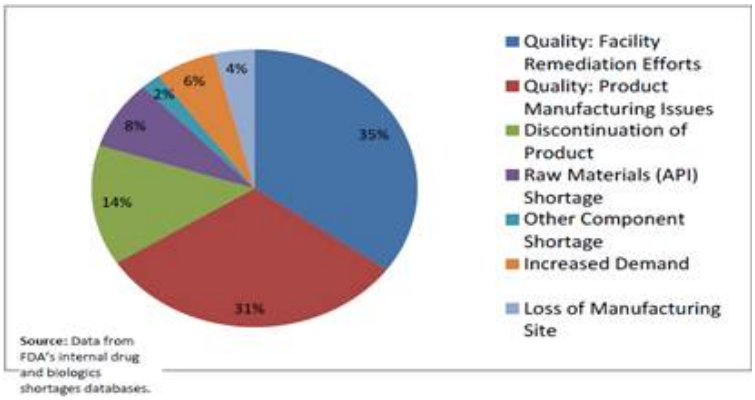
2. U.S. Food and Drug Administration. Strategic plan for preventing and mitigating drug shortages. http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf. Published October 2013. Accessed November 21, 2013.
3. U.S. Food and Drug Administration. FDA Acts to Prevent More Drug Shortages. FDA Consumer Health Information. October 31, 2013. http://www.fda.gov/forconsumers/consumerupdates/ucm370495.htm. Accessed November 21, 2013,
4. Obama Administration takes action to reduce prescription drug shortages in the U.S. [fact sheet]. Washington, DC: Office of the Press Secretary; October 31, 2011. http://www.whitehouse.gov/the-press-office/2011/10/31/fact-sheet-obama-administration-takes-action-reduce-prescription-drug-sh. Accessed November 21, 2013.

Figure 1. U.S. Drug Shortages by Year from 2005 to 2012



Source: FDA Acts to Prevent More Drug Shortages. FDA Consumer Health Information/U.S. Food and Drug Administration. October 2013. http://www.fda.gov/forconsumers/consumerupdates/ucm370495.htm.

Figure 2. Drug Shortages by Primary Reason for Disruption in Supply in 2012



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Year End Table of Contents: Volume 3, issues 11-20

(continued on next page)

• Jacki Dyck-Jones. **Food for Thought: Career Entrees for the Advanced Degree Palate**. *Postscripts*. May 2013;3(14):75
• Kathy Boltz. **Report from Bethesda: AMWA Spring Board of Directors Meeting**. *Postscripts*. Jun 2013;3(15):80
• James Sanchez. **Interview Tips and Tricks with Peggy Wallace**. *Postscripts*. Nov 2013;3(19):156
• James Sanchez. **Medical Publication Planning: A Webinar by Donna Simcoe**. *Postscripts*. Dec 2013;3(20):180

MEETING REPORTS IN PICTURES

• Pictures from the **AMWA Pac-SW Holiday Party**, December 2012. *Postscripts*. Feb 2013;3(11):15
• **Asilomar 2013 Conference** Through Pictures. *Postscripts*. Jun 2013;3(15):85
• Good Food and Laughs at **Chapter's Happy Hour** Last Month. *Postscripts*. May 2013;3(14):74
• Chapter Dinner at **AMWA 2013 Meeting in Columbus**, Ohio. *Postscripts*. Dec 2013;3(20):179

WRITER'S TOOLS

• Dikran Toroser. **AMA-zing Style**. *Postscripts*. Feb 2013;3(11):10 — *Postscripts*. Mar 2013;3(12):31 — *Postscripts*. Apr 2013;3(13):46 — *Postscripts*. May 2013;3(14):68 — *Postscripts.* June 2013;3(15):82 — *Postscripts*. Aug 2013;3(16):108 — *Postscripts*. Sept 2013;3(17):125 — *Postscripts*. Oct 2013;3(18):141 — *Postscripts*. Nov 2013;3(19):160 — *Postscripts*. Dec 2013;3(20):176

List of topics covered in AMAzing Style

- Abbreviations in medical writing (Oct 2012)
- Immunology—an AMA style brief summary (Nov 2012)
- Visual presentation of data in scientific manuscripts (Dec 2012)
- Study design, statistics and types of study (Feb 2013)
- A primer on DNA and amino acids (Mar 2013)
- Commonly Misused Terms in Medical Writing--Correct and Preferred Usage (Apr 2013)
- Health Economics: Cost-effectiveness Analysis, Cost-Benefit Analysis (May 2013)
- Release of Scientific Information to the Public Domain (Jun 2013)
- Numbers and percentages (July 2013)
- Types of articles (Aug 2013)
- Acknowledgements & Disclosures (Sept 2013)
- Acknowledgements & Disclosures (Oct 2013)
- Journal Editors (Nov 2013)
- Copyright and Trademark—a primer (Dec 2013)

• Susan Chang and Alyssa Wu-Zhang. **de-MS-tifying Word**. *Postscripts*. Feb 2013;3(11):9 — *Postscripts*. Mar 2013;3(12):30 — *Postscripts*. Apr 2013;3(13):48 — *Postscripts*. May 2013;3(14):71 — *Postscripts*. Aug 2013;3(16)110 — *Postscripts*. Sept 2013;3(17):127 — *Postscripts*. Oct 2013;3(18):143 — *Postscripts*. Nov 2013;3(19):162 — *Postscripts*. Dec 2013;3(20):178

List of topics covered in de-MS-tifying Word

- Shortcuts for navigating long documents (May 2012)
- Track change user name and initials to facilitate reviews/revisions (Jun 2012)
- Automated features for numbered and alphabetical lists (Nov 2012)
- Track change settings and tips for facilitating document reviews (Dec 2012)
- View, navigate, and troubleshoot formatting problems (Feb 2013)
- Formatting shortcuts, international characters, and autocorrect options (Mar 2013)
- Captioning (tables, figures) and cross referencing (tables, figures, section headings) (Apr 2013)
- "Safe Paste" options for importing text from other sources (May 2013)

(continued on next page)

- Creating customized, electronic tables of content (TOCs) (Jun 2013)
- The mysterious section break: Next page and continuous section breaks (Aug 2013)
- Optimal view settings and synchronous scrolling to compare two documents (Sep 2013)
- Advanced formatting features: Window/orphan control, Keep with next, Keep lines together, and Page break before (Oct 2013)
- Favorite Keyboard Shortcuts (Dec 2013)

AWARDS & HONORS

- **Winner of 2013 Frances Larson Memorial Award For Excellence in Writing - Michelle M. Merrigan**. *Postscripts*. May 2013;3(14):63
- **Deborah Brown Wins Golden Advocate Award**. *Postscripts*. Jun 2013;3(15):81
- **Postscripts from 1996. (Honoring the contributions of Loraine Schacher and Lanie Adamson, long-time members of AMWA Pac-SW chapter)**. *Postscripts*. Aug 2013;3(16):116

CAREER TOOLS

- Irene Yau. **Meet my friend C.A.R.L**. *Postscripts*. Feb 2013;3(11):16
- Haripriya Shankar. **Incredible Mentoring Program Within an Academic Center**. *Postscripts*. Mar 2013;3(12):33
- Irene Yau. **Answering Difficult Interview Questions**. *Postscripts*. Apr 2013;3(13):51
- Irene Yau. **Success**. *Postscripts*. May 2013;3(14):73
- Irene Yau. **Answering Difficult Interview Questions. Part 2**. *Postscripts*. Aug 2013;3(16):114
- Irene Yau. **Get Moving!** *Postscripts*. Oct 2013;3(18):145
- James Sanchez. **Interview Tips and Tricks with Peggy Wallace**. *Postscripts*. Nov 2013;3(19):156
- **Monthly Job Listings** by Irene Yau. *Postscripts*. May 2013;3(14):73 — *Postscripts*. Jun 2013;3(15):93 — *Postscripts*. Aug 2013;3(16):114 — *Postscripts*. Sept 2013;3(17):130 — *Postscripts*. Oct 2013;3(18):146 — *Postscripts*. Dec 2013;3(20):187

PRESIDENT'S DESK, EDITOR'S CORNER

- Jennifer Grodberg. **From the President's Desk**. *Postscripts*. Feb 2013;3(11):4 — *Postscripts*. Mar 2013;3(12):22 — *Postscripts*. Apr 2013;3(13):39 — *Postscripts*. May 2013;3(14):58 — *Postscripts*. Jun 2013;3(15):79 — *Postscripts*. Aug 2013;3(16):98 — *Postscripts*. Sept 2013;3(17):119 — *Postscripts*. Nov 2013;3(19):153 — *Postscripts*. Dec 2013;3(20):169
- Ajay Malik. **Editor's Corner**: Summer Reads and Travels. *Postscripts*. Aug 2013;3(16):101 — The Medical Writers in the Playoff Season. *Postscripts*. Oct 2013;3(18):144

BACKPAGE

- Four Sporting Boys: Basketball. *Postscripts*. Feb 2013;3(11):18 — Meeting on the Turret Stairs. *Postscripts*. Mar 2013;3(12):35 — Little Red Riding Hood by Trina Schart Hyman. *Postscripts*. Apr 2013;3(13):55 — No More Hurting People. . . PEACE. *Postscripts*. May 2013;3(14):76 — My Heart is in Oklahoma. *Postscripts*. Jun 2013;3(15):95 — The Checkered House. *Postscripts*. Sept 2013;3(17):132 — Jimwood Weed. *Postscripts*. Oct 2013;3(18):150 — The History of AMWA. *Postscripts*. Nov 2013;3(19):166 — Morning Talk by Milton Avery, the American Matisse. *Postscripts*. Dec 2013;3(20):188

MISCELLANEOUS

- Victoria Love. **Sneak Peek into the Latest AMWA Journal**. *Postscripts*. Apr 2013;3(13):49
- **Chocolate Hills and Nobel Laureates**. *Postscripts*. Sept 2013;3(17):120
- **Postscripts from 1996**. (Honoring the contributions of long-time members of AMWA Pac-SW chapter Loraine Schacher and Lanie Adamson). *Postscripts*. Aug 2013;3(16):116
- **The History of AMWA**. *Postscripts*. 3(19);166

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DECEMBER JOB LISTING SYNOPSIS

Manager, Medical Writing
Allergan, Inc.

Regulatory Medical Writer
Ambit BioSciences Inc.

Medical Writer, Director
BrandKarma

Medical Writer
ScienceMedia, Inc.

Medical Writing Manager – Bone
Medical Writing Manager - Inflammation
Amgen

Scientific Writer
City of Hope

Technical Copywriter
Glidewell Laboratories

Director Of Medical Writing and Publications
Spectrum Pharmaceuticals

As a reminder, Job Listings are available for current, interested members and are available through the following ways:

- Job openings are sent out on a ~monthly basis through the jobs mailing list
- Job listings will be posted periodically through our LinkedIn SubGroup, AMWA Pacific Southwest Chapter, so be sure to join the group

Please e-mail employment-coordinator@amwa-pacsw.org if you'd like to share any job leads with the group and it will be added to the job listings.

Morning Talk by Milton Avery, the American Matisse

"Morning Talk" by Milton Avery, 1963, oil on canvas, 50 x 60 in (127 x 152.4 cm).
Location: in the private collection of Alice Lawrence (link).

Milton Avery (March 7, 1885 – January 3, 1965) was an American painter and a sketch artist. His paintings with simplified forms and patterns, combined with hues and nuances of just a few colors on canvas elicit deep emotions.

He is considered an American Matisse, partly because of the shades, subtlety and nuances of colors in his landscapes, still life, and subjects he painted. In some of his later work, he used tinted paints and layers of paints giving a veil and shimmering effect.

Like his paintings and drawings, Milton was also a man of few words: "Why say it when you can paint it?"

Standing in front of a Milton's painting is akin to listening to a song from a language that you don't speak. Just as that song teleports the brain from the realm of words to the universe of lyrics, music and rhythm, a Milton also frees viewers from the visual trappings and transports them to the imaginative world deep in the painting.

New York Times art critic, John Canady, once quoted a Cape Cod resident in his article on Milton: "It used to be possible to look out the window and see dunes and sea. Now you look out and you see an Avery."

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- Wikipedia: Milton Avery, Art Students League of New York, Roy Neuberger

— *Editor*